

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparative effectiveness of plantar massage and reflexology foot massage on pain, balance and functional reach among patients with peripheral neuropathy

Protocol summary

Study aim

To find out what is better in reducing neuropathic pain and increasing balance and functional reach between plantar massage and reflexology foot massage among patients with peripheral neuropathy

Design

A randomized clinical trial with two parallel intervention groups, a study of phase 3 with 18 people in each group, 36 in total.

Settings and conduct

Allied hospital Faisalabad General hospital Samanabad

Participants/Inclusion and exclusion criteria

Both genders are between 35 and 60 years old.
Diagnosed patients with grade II peripheral neuropathy.
Ability to stand on both feet. Can perform the given instructions. There was no cardiac problem. No fracture, injury, or amputation of the lower or upper limb. Any neurological problem. No foot or toe ulcer. There is no peripheral thrombosis. Ambulation difficulties or using any walking devices were excluded. No vision impairment.

Intervention groups

Group A: Plantar massage group Group B: Reflexology foot massage group

Main outcome variables

Pain Balance Functional reach

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240311061253N1**

Registration date: **2024-05-10, 1403/02/21**

Registration timing: **prospective**

Last update: **2024-05-10, 1403/02/21**

Update count: **0**

Registration date

2024-05-10, 1403/02/21

Registrant information

Name

Rabeea Saeed

Name of organization / entity

The university of Faisalabad

Country

Pakistan

Phone

+92 303 0449224

Email address

2022-ms-pt-032@tuf.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-15, 1403/02/26

Expected recruitment end date

2024-09-26, 1403/07/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effectiveness of plantar massage and reflexology foot massage on pain, balance and functional reach among patients with peripheral neuropathy

Public title

Effect of plantar massage vs reflexology foot massage on peripheral neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 35 and 60 years
Diagnosed patient of grade II peripheral neuropathy
Ability to stand on both feet
Cooperative patients
Can perform given instructions
Volunteered to participate

Exclusion criteria:
Cardiac problem
upper limb or lower limb amputation at any level
foot or toe ulcer
severe visual impairment
any vestibular disorder
edema, peripheral thrombosis, burn, injury or fracture of lower extremity
ambulation difficulties or using any walking device
neurological disorders, including stroke, parkinson's disease, and dementia

Age
From **35 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple random sampling was used for sample collection. The list of individuals was generated through online randomization generator. According to the list the participants were divided into both groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research and Ethics / Technical committee of The University of Faisalabad

Street address

House no. 68, street no. 1 defence paradise in front of sheikhon wala railway crossing

City

Faisalabad

Postal code

38000

Approval date

2024-02-15, 1402/11/26

Ethics committee reference number

TUF/DR/SA/MSPP/2024/397

Health conditions studied

1

Description of health condition studied

Peripheral neuropathy

ICD-10 code

G90.0

ICD-10 code description

Idiopathic peripheral autonomic neuropathy

Primary outcomes

1

Description

Pain

Timepoint

Pain was measured at 0 weeks before intervention and after the application of the intervention at 3 weeks.

Method of measurement

Self-report version of the Leeds assessment of signs and symptoms of neuropathic pain scale (S-LANSS)

2

Description

Balance

Timepoint

Balance was measured at 0 weeks before intervention and after the application of the intervention at 3 weeks.

Method of measurement

Balance was measured through Berg Balance Scale (BBS)

3

Description

Functional reach

Timepoint

Functional reach was measured at 0 weeks before intervention and after the application of the intervention at 3 weeks.

Method of measurement

Functional reach was measured through functional reach test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: plantar massage. Plantar massage will be given through sensory brush for 3 days per week for 3 weeks. The brush will be held horizontal to the plantar aspect of the foot. Brushing will be done slowly,

never back and forth on the same spot, and with enough pressure to cause the brush's bristles to bend. The goal is to trigger the feet's pressure touch receptors rapidly. Participants will be informed that the therapy might "tickle." Massage will be given for 5 minutes on each foot

Category

Treatment - Other

2**Description**

Intervention group: Reflexology foot massage group. Three weeks of foot reflexology will be conducted, with two sessions each week lasting thirty minutes, 15 minutes for each foot. Applying the reflexology method will involve raising the participant's leg level to the practitioner's chest level. Effleurage massage will be given to the dorsal area, plantar region, tibialis anterior, peroneus longus-brevis, and gastro soleus muscles for five minutes. Effleurage will be utilized to stimulate the autonomic nervous system, and also the reflex mechanism of action, capillaries, and lymphatic function. Reflexology massage will be done according to the following application protocol: solar plexus and diaphragm reflexes, adrenal gland reflexes, the arm and shoulder reflexes, the spine reflexes, the hip, thigh and leg reflexes, the sciatic nerve reflexes, solar plexus and diaphragm reflexes. All of these are done for 7*2 on each foot.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Allied hospital Faisalabad

Full name of responsible person

Anbreena Rasool

Street address

West canal road, Faisalabad

City

Faisalabad

Postal code

38000

Phone

+92 345 7936825

Email

anbreena.rasool@tuf.edu.pk

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

The University of Faisalabad

Full name of responsible person

Anbreena Rasool

Street address

West canal road

City

Faisalabad

Postal code

38000

Phone

+92 345 7936825

Email

anbreena.rasool@tuf.edu.pk

Web page address

https://tuf.edu.pk/

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

The University of Faisalabad

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

The University of Faisalabad

Full name of responsible person

Rabeea Saeed

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

House no. 68, street no. 1 defence paradise in front of sheikhon wala railway crossing

City

Faisalabad

Province

Punjab

Postal code

38000

Phone

+92 313 7709264

Email

2022-ms-pt-032@tuf.edu.pk

Person responsible for scientific inquiries**Contact****Name of organization / entity**

The University of Faisalabad
Full name of responsible person
Rabeea Saeed

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

Street address
House no. 68, street no. 1 defence paradise in front of sheikhon wala railway crossing

City
Faisalabad

Province
Punjab

Postal code
38000

Phone
+92 313 7709264

Email
2022-ms-pt-032@tuf.edu.pk

Web page address

Person responsible for updating data

Contact

Name of organization / entity
The University of Faisalabad

Full name of responsible person
Rabeea Saeed

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

Street address
House no. 68, street no. 1 defence paradise in front of sheikhon wala railway crossing

City
Faisalabad

Province

Punjab
Postal code
38000

Phone
+92 313 7709264

Email
2022-ms-pt-032@tuf.edu.pk

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Comparative effectiveness of plantar massage and the reflexology foot massage on pain, balance and functional reach among patients with peripheral neuropathy

When the data will become available and for how long

Starting 6 months after publication and it will remain available for everyone

To whom data/document is available

This will be available for everyone

Under which criteria data/document could be used

anbreena.rasool@tuf.edu.pk

From where data/document is obtainable

rabeeasaeed@gmail.com +923030449224

What processes are involved for a request to access data/document

Any applicant will just need to contact for the data file at rabeeasaeed@gmail.com or at +923030449224

Comments